REMARKS/ARGUMENTS

The rejections presented in the Office Action dated August 20, 2007 (hereinafter Office Action) have been considered. Claims 1-12, 14, and 35-46 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1-12, 14, and 35-46 are rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,520,176 to *Cohen* (hereinafter "*Cohen*") in view of U.S. Patent No. 6,200,265 to *Walsh et al.* (hereinafter "*Walsh*") and '*Aircraft Noise and Sleep Disturbance: Final Report*', prepared by the *Civil Aviation Authority London* on behalf of *The Department of Trade*, August 1980 (hereinafter "*CAA Report*").

The Applicant's independent claim 1 recites detecting at least one physiological condition and at least one non-physiological condition associated with sleep quality of a patient, the non-physiological condition comprising an ambient condition external to the patient other than time that affects the sleep quality of the patient; and collecting and storing sleep quality data based on the detected conditions, wherein collecting and storing the sleep quality data is performed at least in part by an implantable device.

In addressing the Applicant's independent claims, the Office Action proposes combining the respective disclosures of *Cohen*, *Walsh*, and the *CAA Report*. (Pages 2-3). Specifically, the Office Action relies on *Cohen* for disclosing detecting a physiologic condition associated with sleep quality and the *CAA Report* for detecting a non-physiologic condition associated with sleep quality.

The Office Action acknowledges that *Cohen* and the *CAA Report* each fail to disclose performing any steps implantably. As such, the Office Action relies on *Walsh* to disclose "utilizing implantable devices to detect and store measured physiological data." (Page 3).

The Applicant respectfully submits that even if all of the references disclose the subject matter as alleged in the Office Action, the combination of references still fails to teach or suggest each and every element and limitation of at least independent claim 1.

For example, the Applicant's independent claim 1 claims that collecting and storing the sleep quality data based on a detected non-physiological condition is performed at least in part by an implantable device. *Walsh* only concerns collecting physiological information. (Col. 1, Lines 6-8). *Walsh* does not contemplate collecting and storing sleep quality data based on a detected non-physiological condition, the non-physiological condition comprising an ambient condition external to the patient other than time that affects the sleep quality of the patient.

Even if the *CAA Report* discloses conducting noise measurements at selected sites around airports, the *CAA Report* does not concern doing such implantably. Moreover, the Applicant respectfully asserts that the teachings and suggestions of *Walsh* and the *CAA Report* would provide insufficient guidance for one of ordinary skill in the art having these references before him/her to make a modification of *Walsh* to implantably collect and store sleep quality data based on a detected ambient external non-physiological condition.

None of the cited references disclose implantably collecting and storing sleep quality data based on a detected non-physiological condition, alone or in combination. For at least this reason, the Applicant respectfully submits that the combination of *Cohen*, *Walsh*, and the *CAA Report* fails to teach or suggest implantably collecting and storing sleep quality data based on a detected non-physiological condition, and as such cannot render at least independent claim 1 obvious.

Furthermore, there is no reasonable expectation of success that one skilled in the art could use the teachings of the *CAA Report* to modify the implantable device of *Walsh* to implantably detect aircraft noise. It is unclear how *Walsh's* implantable device, that detects only physiologic signals, could be modified using the teachings of the *CAA Report* to provide implantably collecting and storing sleep quality data based on a detected ambient non-physiological condition external to the patient.

For each of the reasons discussed above, the Applicant respectfully submits that no proper combination of *Cohen*, *Walsh*, and the *CAA Report* teaches or suggests each and every element and limitation of independent claim 1. As such, this combination fails to render at least claim 1 obvious.

The Applicant's independent claim 35 recites detecting at least one physiological condition and at least one non-physiological condition associated with the sleep quality of the patient, the non-physiological condition comprising an ambient condition external to the patient other than time that affects the sleep quality of the patient; collecting sleep quality data based on the detected conditions; and evaluating the sleep quality of the patient using the collected data, wherein at least one of collecting the sleep quality data and evaluating the sleep quality is performed at least in part by an implantable device. The limitations of claim 1 are recited above.

The Applicant respectfully submits that no proper combination of the cited references teaches or suggests that collecting the sleep quality data and evaluating the sleep quality is performed at least in part by an implantable device, wherein collecting and evaluating include collecting and evaluating sleep quality data based on a detected non-physiological ambient condition external to the patient.

Only the *Walsh* reference provides some aspect of an implantable device, and in that way only concerns sensing physiological information. While the *FAA Report* discloses collecting external airport noise, these teachings would not be properly combinable to account for all of the Applicant's independent claim limitations.

For example, as discussed above, the combination of the cited references fails to teach or suggest collecting and storing sleep quality data based on a detected non-physiological condition, the non-physiological condition comprising an ambient condition external to the patient other than time that affects the sleep quality of the patient.

Moreover, the references cannot be properly combined to provide that collecting of the non-physiological data occurs external to the patient, where the non-physiological data is then transmitted into an implantable device and evaluating the sleep quality is performed at least in part by the implantable device. None of the cited references disclose transferring collected data to an implantable device, and *Walsh* teaches away from modifying an embodiment so that collected data is transmitted into an implantable device for processing, as discussed below.

As discussed above, only the *Walsh* reference discusses an implantable device. While *Walsh* discloses sensing physiological data using the implantable device and transmitting the data to an external device (Abstract), *Walsh* does not disclose transmitting collected data into the implantable device. Therefore, the combination of *Cohen*, *Walsh*, and the *CAA Report* fails to teach or suggest collecting non-physiological data external to a patient and transmitting the collected non-physiological data to an implantable device for evaluation.

Moreover, *Walsh* teaches away from collecting physiological data external to a patient and transmitting the collected data to an implantable device for evaluation.

The Applicant notes that the United States Supreme Court affirmed in the recent *KSR Intern Co. v. Teleflex* decision addressing obviousness under §103(a) that a *prima facie* case of obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. (127 S.Ct. 1727, 1740 (U.S. 2007) citing *United States v. Adams*, 383 U.S. 39, 40 (1966); *see also* MPEP § 2144.05(III) discussing *In re Geisler*, 116 F.3d 1465, 1471 (Fed. Cir. 1997)).

The *Walsh* reference is primarily concerned with implantably sensing physiological data and utilizing an external device in wireless communication with the implantable device for expanded memory storage and processing. (Col. 1, Lines 6-12; Col. 8, Lines 47-51; Col. 9, Lines 1-6; Col. 10, Lines 30-35). *Walsh* seeks to use an external device for storage and processing of data because:

> A problem well known to designers of implantable medical devices, such as pacemakers, for example, concerns the necessity to use low power components, including low power memory components, within the implantable medical device. Use of low power components is considered necessary in order to provided for extended periods of implantable electronic device operation and to reduce the need to repeatedly replace batteries which can only be accomplished through surgical means. As a consequence, conventional implantable medical devices typically employ

> low voltage, low current memory devices which have limited storage capacity and access speed, and often lag behind the state-of-the-art in memory technology by several years. These and other limitations significantly decrease the data storage and access capability of implantable medical devices, and often precludes the opportunity to integrate high capacity, low cost, state-of-the-art memory devices in implantable medical device designs. (Col. 1, Lines 33-49, emphasis added; *See also* Col. 1, Lines 28-31; Col. 8, Lines 54-63; Col. 9, Lines 26-34).

As such, *Walsh* clearly teaches away from collecting data using a patient external device and transmitting the collected data to an implantable device for evaluation, as such an embodiment would further frustrate each of the identified problems which the *Walsh* reference is directed toward addressing. (*KSR Intern Co.,* 127 S.Ct. at 1740; *see also In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000) (proposed modification must not be made in the abstract but rather made in view of the entire teaching of the prior art). As such, the Applicant respectfully submits that no proper combination of *Cohen*, *Walsh*, and the *CAA Report* teaches or suggests each and every element and limitation of independent claims 1 and 35.

Furthermore, the Office Action states that it "would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a device as disclosed by Walsh, in the system of Cohen, because such a combination would not produce any unexpected results, but would merely be a combination of elements known in the art at the time of the invention." (Page 3). While disputing the veracity of the statement, the Applicant notes that no reason for making the proposed combination is actually asserted. The lack of unexpected results alone would not provide one of ordinary skill in the art with guidance or motivation to make the proposed modification. As such, the Applicant respectfully submits that it is unclear why one of ordinary skill in the art would make the proposed modification without improperly gleaning information from the Applicant's disclosure.

For each of the reasons discussed above, the Applicant respectfully submits that no proper combination of *Cohen*, *Walsh*, and the *CAA Report* teaches or suggests each and every element and limitation of independent claims 1 and 35.

Each of claims 2-12, 14, and 36-46 depend from one of independent claims 1 and 35, respectively. Independent claims 1 and 35 are not obvious for at least the reason that the cited references fail to teach or suggest each and every limitation recited in each claim. Furthermore, while the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 35. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent claims 2-12, 14, and 36-46 are not made obvious by *Cohen,* even in combination with *Walsh* and the *CAA Report*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 1-12, 14, and 35-46 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending claims and the inability to combine the teachings in a proper manner that accounts for the Applicant's claim elements and limitations. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.058PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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